

2596-151

12/21/2009

1/10



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DEC 21 2009

Ms. Heather Masch
Regulatory Affairs Associate
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094-3688

RE: Notification of Alternate Brand Name to: Hartz® InControl® Flea & Tick Topical Drops
for Dogs (&) (and) (Puppies) (Weighing) (4 to 15 lbs.)
EPA Registration Number: 2596-151
Date of Submission: November 9, 2009

Dear Ms. Masch:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated, November 9, 2009, for the above mentioned product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please me directly at 703-305-6249 or Joyce Edwards of my staff at 703-308-5479.

Sincerely,

Linda Arrington
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs

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United States
Environmental Protection Agency
 Washington, DC 20460

registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2596-151	2. EPA Product Manager R. Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) HARTZ Reference 119	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094-3688 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	NOTIFICATION DEC 21 2009
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.	
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.	

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

"Addition of alternate brand names per PR Notice 98-10"

"This notice is consistent with the provisions of PR Notices 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the Confidential Statement of Formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container If "Yes" Package wgt No. per container			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Heather Masch	Title Regulatory Affairs Associate	Telephone No. (include Area Code) 201-271-4800, ext. 7036
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Affairs Associate	
4. Typed Name Heather Masch	5. Date 11/9/09	



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094 201/271-4800
REGULATORY AFFAIRS

November 9, 2009

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: Mr. Richard Gebken (PM # 10)
RE: HARTZ Reference 119
EPA Reg. No. 2596-151
Addition of alternate brand names per PR Notice 98-10

Dear Mr. Gebken:

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688 is filing this notification to add new alternate brand names for the product.

The Hartz Mountain Corporation is submitting the following information:

- A completed application (EPA Form 8570-1) and;
- Three copies of the proposed notification label.

"This notice is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR §152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Sincerely,

A handwritten signature in black ink, appearing to read "H Masch".

Heather Masch
Regulatory Affairs Associate

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Hartz® Reference 119

NOTIFICATION

DEC 21 2009

Alternate Brand Names

Hartz® InControl® Flea & Tick Topical Drops for Dogs (&) (and) (Puppies) (Weighing) (4 to 15 lbs.)

- Hartz® InControl® Flea & Tick Topical Drops for Dogs (&) (and) (Puppies) (Weighing) (>4 to 15 lbs.)
- Hartz® InControl® Flea & Tick Topical Drops for Dogs (&) (and) (Puppies) (Weighing) (16 to 30 lbs.)
- Hartz® InControl® Flea & Tick Topical Drops for Dogs (&) (and) (Puppies) (Weighing) (31 to 60 lbs.)
- Hartz® InControl® Flea & Tick Topical Drops for Dogs (&) (and) (Puppies) (Weighing) (over 60 lbs.)

Hartz® UltraGuard™ Flea (&) (and) Tick Drops for Dogs [for Dogs (&) (and) (Puppies) (Weighing) >4 to 15 lbs.])

- Hartz® UltraGuard™ Flea (&) (and) Tick Drops for Dogs [for Dogs (&) (and) (Puppies) (Weighing) 4 to 15 lbs.])
- Hartz® UltraGuard™ Flea (&) (and) Tick Drops for Dogs [for Dogs (&) (and) (Puppies) (Weighing) 16 to 30 lbs.])
- Hartz® UltraGuard™ Flea (&) (and) Tick Drops for Dogs [for Dogs (&) (and) (Puppies) (Weighing) 31 to 60 lbs.])
- Hartz® UltraGuard™ Flea (&) (and) Tick Drops for Dogs [for Dogs [(&) (and) Puppies (Weighing) Over 60 lbs.])

ACTIVE INGREDIENT

Phenothrin.....	85.7%
OTHER INGREDIENTS.....	14.3%
TOTAL.....	100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for (ingredients and) additional precautionary statements

NET CONTENTS Contains (*number*) tubes, each __ fl. oz. (__ ml)
 [Note: Multiple packages containing from 1 tube to X tubes – each tube contains fl. oz. (__ ml)]

For Dogs and Puppies Weighing:	Net Contents (Each tube)
4 to 15 lbs.	0.04 fl. oz. (1.1 ml)
16 to 30 lbs.	0.04 fl. oz. (1.3 ml)
31 to 60 lbs.	0.14 fl. oz. (4.1 ml)
> 60 lbs.	0.20 fl. oz. (5.9 ml)

EPA Reg. No. 2596-151

MASTER LABEL BASED ON 9/6/07 EPA STAMPED APPROVED LABEL

EPA Est. No. 2596-NJ-1

[Made (in the U.S.A.) (by)]
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094 (U.S.A.)

**READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS OR ON PUPPIES 12 WEEKS OF AGE OR OLDER
DO NOT USE ON DOGS OR PUPPIES WEIGHING 4 LBS. OR LESS.**

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco.

HAZARDS TO DOMESTIC ANIMALS

DO NOT USE ON CATS OR KITTENS. Do not use on puppies less than 12 weeks old. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing animals. Sensitivity such as slight transitory redness of the skin at the site of application may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

ENVIRONMENTAL HAZARDS: This product is toxic to fish.

FIRST AID

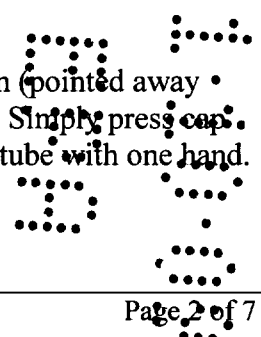
If in eyes: • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice. • You may also contact 1-800-275-1414 for emergency medical treatment information. • Have the product container or label with you when calling for advice or going for treatment.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

[The application steps below may optionally be numbered or bulleted to clarify the order, depending on the final physical layout of the label.]

Remove one applicator tube from the package and hold in an upright position (pointed away from your face). (Pull off cap, turn the cap around and place on top of tube. Simply press cap down to break the seal of the tube. Remove cap carefully.) (Hold bottom of tube with one hand. With the other hand, snap cap off.)



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MASTER LABEL BASED ON 9/6/07 EPA STAMPED APPROVED LABEL

Position the tip of the tube on the dog's back between the shoulder blades. Use the tip of the tube to part the dog's hair so that the product will be applied at skin level. Begin squeezing out the contents of the tube to form a stripe as you move from the shoulder blades along the dog's back to the base of the tail. Repeat every month.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal. Store in a cool, dry place. **If empty:** Do not reuse the container. Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain. **Container Disposal:** Nonrefillable container. Do not reuse or refill this container.

INDIVIDUAL TUBE TEXT

Hartz® InControl® Flea & Tick Topical Drops for Dogs (& (and) Puppies)
Hartz® UltraGuard™ Flea (& (and) Tick Drops for Dogs (& (and) Puppies)

[Product name will be followed by weight of dog for which tube is intended]

KEEP OUT OF REACH OF CHILDREN

CAUTION: Read accompanying label before use.

[Active Ingredient:]

Phenothrin.....85.7%

Range of volumes from 0.04 fl. oz. (1.1 ml) to 0.20 fl. oz. (5.9 ml) depending upon size of dog

EPA Reg. No. 2596-151

EPA Est. No. 2596-NJ-1

The Hartz Mountain Corp.

OPTIONAL/ALTERNATE LABEL TEXT

(Kills) (& (and) (Repels) (Fleas) (& (and) (Ticks) for (up to) (30 days) (1 month) (4 weeks)

(Kills) (& (and) (Repels) (Fleas) (& (and) (Ticks) through contact for (up to) (30 days) (1 month) (4 weeks)

Kills (Fleas) (& (and) (Ticks) (& (and) (mosquitoes) for (up to) (30 days) (1 month) (4 weeks)

Kills (Fleas) (& (and) (Ticks) (& (and) (mosquitoes) through contact for (up to) (30 days) (1 month) (4 weeks)

(Starts killing) (fleas) (& (and) (ticks) (and) (& (mosquitoes) (through contact)

(Starts to kill) (fleas) (& (and) (ticks) (and) (& (mosquitoes) (through contact)

Controls (Fleas) (& (and) (Ticks) (& (and) (mosquitoes)

Contains an adulticide

Kills adult (Fleas) (& (and) (Ticks) (& (and) (mosquitoes)

Kills fleas before they lay eggs

One tube gives (provides) (30 days)(4 weeks)(one month of) protection

Kills (and) (& (repels) fleas which may cause (flea bite anemia) (and)(or)(flea allergy dermatitis)

Kills (and) (& (repels) fleas that may transmit tapeworm infestation

Flea (and) (& tick topical treatment

(Controls) (kills) (repels) adult fleas (and)(&) ticks (mosquitoes) round-the-clock for up to (30 days)

(1 month) (4 weeks)

Controls (kills) (repels) up to (30 days) (1 month) (4 weeks)

Flea & tick control

Controls flea and tick infestations

Controls (kills) (repels) up to 30 days (1 month) (4 weeks)

Flea tick (and mosquito) control for (dogs) (and) (or) (puppies)

Flea control for dogs



[The above graphic will be used to depict “do not use on cats” language]

Hartz Ref. 119 (alternate brand name) provides relief from flea infestations for one month by controlling (killing) and preventing adult fleas on your (dog) (and) (puppy).

For Dogs (& (and) Puppies weighing over 4 lbs.

For Dogs (and) Puppies (weighing) (4-15 lbs) (4-30 lbs) (16 - 30 lbs.) (31 - 45 lbs.) (46-60 lbs.) (61 - 90 lbs.) (over 90 lbs.)

MASTER LABEL BASED ON 9/6/07 EPA STAMPED APPROVED LABEL

For (dogs) (and) (or) puppies) over 12 weeks of age

For (dogs) (and) (or) puppies) over 4 lbs.

Special formula for dogs

Specially formulated for dogs

Hartz Ref. 119 (alternate name brand) contains (an insecticide to kill adult fleas and ticks) (and mosquitoes) [an insecticide that kills adult fleas and ticks (and mosquitoes)].

(This product)(alternate brand name) is most effective when used as part of a total program aimed at reducing fleas and ticks (in the dog's environment)

Be sure to treat the animal's bedding and surroundings with a product registered for these uses, such as Hartz® (UltraGuard) (alternate brand name)

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

(30 days) (1 month) Protection

Fresh scent

(Provides)(X Months)(X Days)(X Weeks) Protection

X month supply

1st dose, 2nd dose, 3rd dose, Xth dose

first month, second month, third month, Xth month

X monthly treatments

Triple pack

Value pack

Advanced Care™

(Baby) Fresh (scent) (fragrance)

(Baby) Powder (scent) (fragrance)

Pleasant (scent) (fragrance)

(baby) fresh (scent) (fragrance)

(Baby) Clean (scent) (fragrance)

No mess

This product (package) contains X monthly doses, each ___ fl. oz. (___ ml)

Hartz (brand name) products are designed to complement each other in an integrated program for flea & tick management. To assure proper treatment, we recommend use of (only)

Hartz (Brand name) products

After application, the treated area may appear wet or oily for up to 24 hours.

(As with all flea and tick products, they are)[Hartz Ref. 119 (alternate name brand) is] most effective when used as a part of a total program aimed at reducing fleas and ticks (and mosquitoes) in the (dog's) (and) (or) (puppy's) environment.

Be sure to treat the animal's bedding and surroundings with products registered for these uses, such as the Hartz (alternate name brand) Line.

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MASTER LABEL BASED ON 9/6/07 EPA STAMPED APPROVED LABEL

Adult fleas spend virtually all of their time on your pet.

Once fleas are (apparent) (visible) on your pet, there is already an infestation of their pre-adult stages in your home.

Apply as a stripe from head to tail (total body) flea and tick (and mosquito) protection (control)
Apply as a stripe - spreads over the dog's complete body from head to tail through the natural motion of the animal

Spreads naturally with (dog's) movement (skin and hair oils)

Special formula for (dogs) (and) (or) (puppies)

Specially formulated for (dogs) (and) (or) (puppies)

After application, through its natural movement, your pet's skin and hair oils carry Hartz Ref. 119 (alternate name brand) over the pet's body for protection against fleas (and) ticks, (and)(mosquitoes).

Immediately the (dog's) (and) (or) (puppy's) skin and hair oils will begin to carry this solution over the (dog's) (and) (or) (puppy's) entire body, killing fleas (and) ticks, (and)(mosquitoes).

Initially, to kill existing adult flea populations, you may need to treat the home, pet's bed and yard with traditional flea products such as home sprays, foggers, and/or yard & kennel sprays. Hartz Ref. 119 (alternate name brand) can be used in conjunction with the entire (brand name) product line.

Wait 48 hours after applying before bathing your dog.

Do not bathe your cat for 48 hours after application.

Water Resistant

May stain leather and suede fabrics for (24)(24 to 48) hours after application.

To help remind you when you last applied treatment, simply write in the date when each dose is applied.

First Dose _____

Second Dose _____

Third Dose _____

Xth Dose: _____

For more information our experts at 1-800-275-1414 (weekdays, 9 am – 5 pm E.S.T.)

VISIT (OUR) (WEBSITE)

(www.hartz.com)(www.hartzultraguard.com)(www.hartzincontrol.com)

Hartz recommends that you visit your veterinarian twice a year.

Hartz® Reference 119
EPA Reg. No.: 2596-151

11/9/09

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MASTER LABEL BASED ON 9/6/07 EPA STAMPED APPROVED LABEL

Hartz® and other trademarks are trademarks of the Hartz Mountain Corporation